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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,932

02/20/2004

Michael N. Helmus

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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,932	Applicant(s) HELMUS ET AL.	
	Examiner ANAND U. DESAI	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-37 is/are pending in the application.
- 4a) Of the above claim(s) 3, 8-18, 20-24 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 19, 25, 27-32, 34-37 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 21, 2007 has been entered.
2. Claims 3, 8-18, 20-24, and 33 have been withdrawn previously.
3. Claims 1, 2, 4, 5, 19, 25-32, and 34-37 are currently under examination.

Withdrawal of Rejections

4. The rejection of claims 1, 2, 4, 5, 26, 28, 31, 34, and 35 under 35 U.S.C. 102(b) as being anticipated by Kleinman et al. (Biochemistry 21: 6188-6193 (1982)) is withdrawn based on the amendment to recite covalently bonded peptide with at least one polysaccharide and/or proteoglycan subunit.
5. The rejection of claims 27, and 29 under 35 U.S.C. 102(b) as being anticipated by Chudzick et al. (U.S. Patent 6,410,044 B1) is withdrawn based on the amendment to recite covalently bonded peptide with at least one polysaccharide and/or proteoglycan subunit.

Maintenance of Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4, 5, 25, 27-32, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuel et al. (Human Gene Therapy 13: 791-802 (2002)).

Samuel et al. disclose the delivery of plasmid DNA to articular chondrocytes via collagen-glycosaminoglycan (GAG) matrices. Collagen-GAG matrices are composed of collagen type I, and chondroitin-6-sulfate that has been cross-linked with 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide (EDC) (see page 792, Materials and Methods, Preparation of collagen-GAG matrices). The claims are reasonably interpreted such that the bioactive polymer can be the same biocompatible polymer, because withdrawn claim 3 is drawn to an embodiment where the polymers are explicitly recited as different. Therefore, Samuel et al. discloses a cross-linked collagen-GAG matrix, wherein the collagen-GAG is the bioactive polymer comprising a RGD protein (collagen) and a proteoglycan subunit (chondroitin-6-sulfate), as well as the cross-linked collagen-GAG matrix is a biocompatible polymer because it is implanted and tolerated. The polymer is a miscible blend of collagen and chondroitin-6-sulfate. Applicant's disclosure of

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figure 1 describes a graft as a covalent linkage between the biocompatible polymer and the bioactive polymer, therefore the covalent cross-linking of the collagen-GAG matrix is reasonably interpreted as encompassing a graft polymer.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

8. Claims 1, 2, 4, 5, 19, 28, 31, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Burg (U.S. Patent 6,991,652 B2).

Burg discloses the use of a biocompatible composite for use in a living subject for purposes of repairing damaged tissues and reconstructing a new tissue. The composite comprises a biocompatible construct selected from the group consisting of polylactide, polyethylene glycol, polycaprolactone, polycolide, polydioxanone, and derivative and copolymers thereof. The comprises a coating of material selected from the group consisting of fibronectin, vitronectin, collagens, polylysine, laminins, alginate-RGD hydrogel, and

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polypeptides derived from extracellular matrices. The alginate-RGD hydrogel is a covalently bonded peptide polysaccharide subunit.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

9. Claims 1, 2, 4-6, 19, 25, 26, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyamoto (U.S. 2004/0136977 A1; previously cited).

Miyamoto describes a crosslinked elastin, wherein the crosslinking starting material further comprises one or more components selected from among proteins such as collagen, gelatin, fibronectin, fibrin, laminin, casein, keratin, sericin and thrombin, polyamino acids such as polyglutamic acid and polylysine, sugars such as polygalacturonic acid, heparin, chondroitin sulfate, hyaluronic acid, dermatan sulfate, chondroitin, dextran sulfate, sulfated cellulose, alginic acid, dextran, as well as polymethyl methacrylate, polydimethylsiloxane, polytetrafluoroethylene, silicone, polyurethane, polyethylene terephthalate, polypropylene, polyethylene, polycaprolactone, polypropylene ether, polytetramethylene glycol, polyethylene

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glycol, polylactic acid, polyvinyl alcohol and polymalic acid (see claim 2). The components are chemically bonded (see claim 8).

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Response to Remarks

10. Applicants state Miyamoto et al. does not disclose or suggest at least one peptide and/or protein subunit covalently bonded to at least one polysaccharide and/or proteoglycan subunit as presently claimed. Applicant's arguments filed December 21, 2007 have been fully considered but they are not persuasive. Claim 8 of Miyamoto (US 2004/0136977) does disclose the chemically bonding as currently pending claims recite.

Claim Objections

11. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 15, 2008

/Anand U Desai, Ph.D./

Patent Examiner, Art Unit 1656